Complete Summary

GUIDELINE TITLE

Massachusetts guidelines for adult diabetes care.

BIBLIOGRAPHIC SOURCE(S)

Massachusetts Department of Public Health: Diabetes Control Program, Diabetes Guidelines Work Group. Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health; 2001 Jun. Various p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Impaired glucose homeostasis
  - Impaired fasting glucose (IFG)
  - Impaired glucose tolerance (IGT)
- Gestational diabetes mellitus (GDM)

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To develop uniform guidelines that apply to adults with diabetes regardless of their insurer
- To help eliminate any confusion brought about by differences in guidelines disseminated by individual third party payers
- To assist health care professionals in systematizing the care provided to people with diabetes

TARGET POPULATION

Adults in Massachusetts with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Diagnosis

1. Testing for diabetes in asymptomatic, undiagnosed individuals
2. Laboratory diagnostic testing
    - Fasting plasma glucose (FPG) (preferred)
    - Casual plasma glucose
    - Oral glucose tolerance test (OGTT)

Treatment

Type 1

1. Oral medications
    - First generation sulfonylureas (tolbutamide, chlorpropamide, tolazamide, acetohexamide)
    - Second generation sulfonylureas (glipizide, glipizide extended release, glyburide, glyburide [micronized], glyburide/metformin, glimepiride)
    - Meglitinides (repaglinide, nateglinide)
    - Alpha glucosidase inhibitors (acarbose, miglitol)

- Biguanides (metformin, metformin extended release, glyburide/metformin)
- Thiazolidinediones* (rosiglitazone, pioglitazone)

*Note: Troglitazone (Rezulin) was removed from the market in March 2000 by the U.S. Food and Drug Administration (FDA) after being linked to liver failure, liver transplants, and deaths.

2. Insulin
    - Very short acting (lispro/humalog)
    - Short acting (Regular)
    - Intermediate acting (Neutral protamine Hagedorn [NPH]/Lente)
    - Long acting (insulin glargine)
    - Long acting (Ultralente)

Type 2

1. Self-management counseling
2. Medical nutrition therapy
3. Physical activity
4. Weight reduction
5. Use of oral glucose lowering agents or insulin if necessary

Management

1. Review of medications and doses
    - Aspirin therapy*
    - Angiotensin-converting enzyme (ACE) inhibitor, if indicated

*Note: There continues to be controversy in the literature regarding the interaction between aspirin therapy and ACE inhibitors.

2. Weight/body mass index (BMI)
3. Blood pressure
4. Laboratory testing
    - Glycated hemoglobin (HbA1c)
    - Fasting/random glucose
    - Urine microalbumin
    - Fasting lipid profile
    - Creatinine
    - Thyroid function tests
    - Electrocardiogram (EKG)
5. Thyroid assessment
6. Review of blood glucose records
7. Counseling
    - Smoking cessation
    - Diabetes self-management (Review nutrition/physical activity plans or referral)
    - Psychosocial adjustment (Suggest support groups or referral)
    - Sexuality/impotence/erectile dysfunction (Discuss diagnostic evaluation and therapeutic options)
    - Preconception/pregnancy (Need for tight glucose control 3 to 6 months preconception; consider early referral to obstetrician/gynecologist)

8. Foot examination
    - Protective sensation
    - Vascular status
    - Skin integrity
    - Foot structure/biomechanics
9. Dilated eye exam
10. Assessment of smoking status
11. Comprehensive lower extremity examination
12. Diabetes education/nutrition referral
13. Dental examination
14. Immunizations
    - Flu vaccine
    - Pneumovax

Prevention of Diabetes-Related Complications

1. Cardiovascular risk reduction
    - Assessment of cardiovascular risk based on lipoprotein levels
    - Treatment based on low-density lipoprotein (LDL) levels
        - Medical nutrition therapy
        - Angiotensin-converting enzyme (ACE) inhibitor therapy
        - Aspirin therapy
        - Smoking intervention model
2. Diabetic nephropathy screening and management
    - Screening for microalbuminuria:
        - Spot collection
        - 24 hour collection
        - Timed collection
    - Hypertension control
        - Lifestyle modifications (weight loss, exercise, reduction of salt and alcohol)
        - Medication management (angiotensin-converting enzyme inhibitors [ACE] and other antihypertensive agents)
3. Foot-related conditions associated with ulcers and amputations
    - Assessment of risk factors
    - Management of at-risk patients

MAJOR OUTCOMES CONSIDERED

- Rates of diabetes-related complications or conditions
- Cost of diabetes-related care in the State of Massachusetts

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not stated

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were developed by a Work Group convened by the Massachusetts Department of Public Health Diabetes Control Program and its Advisory Board. The Work Group was comprised of clinicians, representatives from managed care organizations, the Division of Medical Assistance, the Massachusetts League of Community Health Centers, the Massachusetts Medical Society, and MassPRO. Their recommendations were incorporated into the final version.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnosis and Classification of Diabetes Mellitus

Criteria for Testing for Diabetes in Asymptomatic, Undiagnosed Individuals

Testing for diabetes should be considered for all individuals age 45 and older and, if normal, should be repeated at 3-year intervals. Testing should be considered at a younger age, or be carried out more frequently, in individuals who:

- Are obese (refer to body mass index [BMI] weight table in the original guideline document)
- Have a first-degree relative with diabetes
- Are members of a high-risk ethnic population (African American, Hispanic, Native American, Asian)
- Have delivered a baby weighing >9 pounds or were diagnosed with gestational diabetes mellitus (GDM)
- Are hypertensive (blood pressure $\geq$140/90)
- Have a high density lipoprotein (HDL) cholesterol level $\leq$40 mg/dl, and/or a triglyceride level $\geq$150 mg/dl
- Had impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) on previous testing

The fasting plasma glucose (FPG) is the preferred diagnostic test due to its ease of administration, convenience, acceptability to patients, and lower cost.

Diagnostic Criteria for Diabetes

An FPG $\geq$126 mg/dl (confirmed by testing on two different occasions) is diagnostic for diabetes. The new diagnostic cutpoint (FPG $\geq$126 mg/dl) is based on the observation that this degree of hyperglycemia usually reflects a serious metabolic abnormality that has been shown to be associated with serious complications. The revised criteria are for diagnosis and are not treatment criteria or goals. The glycated hemoglobin (HbA1c) is not recommended for diagnosis at this time.

Criteria for the Diagnosis of Diabetes

	Fasting Plasma Glucose (FPG)[1] (preferred)	Casual Plasma Glucose[2]	Oral Glucose Tolerance Test (OGTT)[3]
Diabetes Mellitus	FPG $\geq$ 126 mg/dl (7.0 mmol/l)	Casual plasma glucose 200 mg/dl (11.1 mmol/l)[4] plus symptoms	Two-hour plasma glucose (2hPG) $\geq$ 200 mg/dl
Impaired	Impaired Fasting		Impaired Glucose

Glucose Homeostasis	Glucose (IFG) FPG ≥ 110 and <126 mg/dl		Tolerance (IGT) 2hPG ≥ 140 and <200 mg/dl
Normal	FPG <110 mg/dl		2hPG <140 mg/dl

[1]The FPG is the preferred test for diagnosis, but any one of the three listed is acceptable. Fasting is defined as no caloric intake for at least 8 hours.
[2]Casual is defined as any time of day without regard to time since last meal. Symptoms are the classic ones of polyuria, polydipsia, and unexplained weight loss.
[3]Oral glucose tolerance test should be performed using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. The OGTT is not recommended for routine clinical use.
[4]If casual plasma glucose ≥160 mg/dl, patient requires diagnostic evaluation for diabetes.

Classification of Diabetes

Type 1

Type 1 diabetes most often results from a cellular mediated autoimmune destruction of the beta cells of the pancreas. Patients with this form of diabetes are dependent upon insulin for survival and are at risk for ketoacidosis. Type 1 commonly occurs in childhood and adolescence but may occur at any age.

Type 2

Individuals with type 2 diabetes have insulin resistance and relative, rather than absolute, insulin deficiency. Primary treatment centers on weight loss, improved nutrition, and increased age-appropriate physical activity. Oral agents may become necessary if the initial treatment is unsuccessful. These patients do not need insulin to survive but may require insulin over time for optimal management, especially if oral agents become ineffective. Type 2 diabetes commonly goes undiagnosed for years because it is often asymptomatic in its early stages. Individuals with undiagnosed type 2 diabetes are at increased risk for developing macro- and microvascular complications.

IFG and IGT

A new stage of impaired glucose homeostasis called impaired fasting glucose (IFG) has been defined as a fasting plasma glucose (FPG) of ≥ 110 mg/dl but <126 mg/dl. The stage called impaired glucose tolerance (IGT) is defined as an oral glucose tolerance test (OGTT) value of ≥140 mg/dl but <200 mg/dl. Although not clinical entities in their own right (in the absence of pregnancy), they are risk factors for future diabetes and cardiovascular disease.

GDM

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. The definition applies regardless of whether insulin or only dietary modification is used for treatment. Gestational diabetes mellitus complicates approximately 4% of all pregnancies in the U.S.; however, the prevalence is higher among some minority groups. Six weeks or more after the pregnancy ends, a woman with GDM should be tested to rule out type 1 or 2 diabetes or impaired fasting glucose/impaired glucose tolerance. Women with GDM have a higher risk for type 2 diabetes later in life.

Goals for Glycemic Control

	Normal	Goal	Action Suggested
Fasting/Before Meals	<110 mg/dl	80-120 mg/dl	<80 or >140 mg/dl
Before Bedtime	<120 mg/dl	100-140 mg/dl	<100 or >160 mg/dl
Hemoglobin A1C	<6%	<7%	>8%

Diabetes Medications

Oral Medications (see original guideline document for dosages)
Regular testing of blood glucose and HbA1c is recommended to assess medication effect.

First Generation Sulfonylureas[1]

- Tolbutamide (Orinase)
- Chlorpropamide (Diabenese)
- Tolazamide (Tolinase)
- Acetohexamide (Dymelor)

Second Generation Sulfonylureas[1]

- Glipizide (Glucotrol)
- Glipizide extended release (Glucotrol XL)
- Glyburide (Micronase, Diabeta)
- Glyburide (micronized) (Glynase PresTab)
- Glyburide/metformin (Glucovance)
- Glimepiride (Amaryl)

Meglitinides

- Repaglinide (Prandin)
- Nateglinide (Starlix)

Alpha Glucosidase Inhibitors

- Acarbose (Precose)
- Miglitol (Glyset)

Biguanides

- Metformin (Glucophage)
- Metformin extended release (Glucophage XR)
- Glyburide/metformin (Glucovance)

Thiazolidinediones[2]

- Rosiglitazone (Avandia)
- Pioglitazone (Actos)

[1]Sulfonylureas act by stimulating endogenous insulin production by the pancreas. Proper selection, dosages, and patient education are important to avoid hypoglycemic episodes. The most common side effects, aside from hypoglycemia, are gastrointestinal (GI) disturbances, which tend to be dose related and disappear when dosage is decreased. Sulfonylureas have been associated with rare occurrences of cholestatic jaundice and hepatitis; if either condition occurs, the sulfonylurea should be discontinued. All sulfonylureas are contraindicated in diabetic ketoacidosis (DKA).
[2]Troglitazone (Rezulin) was removed from the market in March 2000 by the U.S. Food and Drug Administration (FDA) after being linked to liver failure, liver transplants, and deaths.

Insulin
Regular testing of blood glucose and HbA1c is recommended to assess medication effect.

- Very short acting (lispro/humalog)
- Short acting (Regular)
- Intermediate acting (Neutral protamine Hagedorn [NPH]/Lente)
- Long acting (insulin glargine)
- Long acting (Ultralente)

Reduced hyperglycemia and an improvement in glucose toxicity will occur in type 2 diabetes, given sufficient doses of insulin. Individuals with moderately severe type 2 disease, defined as a fasting plasma glucose 140–200 mg/dl, will often show sufficient response to a single or twice-daily dose of insulin.

One study has suggested that bedtime administration is most effective when using intermediate-acting insulin. Another study suggested that 9:00 p.m. is a reasonable time for the single daily insulin dose when used in combination with sulfonylureas. The former study reported improved glycemic control, and the latter study reported less weight gain with the bedtime or evening insulin doses when compared to morning insulin doses.

Individuals with severe type 2 diabetes, defined as a fasting plasma glucose >200 mg/dl, or those who have proved not responsive to the above-mentioned

regimens, may require frequent insulin dosing. This usually requires the addition of short-acting insulin before meals.

The total daily insulin doses for type 2 diabetes may range from 0.4–1.2 U/kg/day. Please be aware that in insulin-resistant patients, doses of >1.5 U/kg/day may be required.

Total daily dosage for people with type 1 diabetes may range from 0.3-0.5 U/kg/day.

The degree of glucose lowering is dose-related. Studies have demonstrated a lowering of fasting glucose of up to 190 mg/dl from baseline in patients with type 2 diabetes treated with insulin.

Type 2 Diabetes Treatment Approach Principles

Optimal treatment for type 2 diabetes incorporates a multiple risk factor approach including self-management counseling, medical nutrition therapy, physical activity, weight reduction if appropriate, and the use of oral glucose lowering agents or insulin if necessary. Careful consideration needs to be given to ameliorating associated cardiovascular risk factors such as hypertension, smoking, and dyslipidemia.

When setting treatment goals for individuals with type 2 diabetes, it is important to consider the person´s ability to comprehend the regimen and assess the risk for severe hypoglycemia. Consider as well other factors that may optimize or minimize the treatment´s benefit including: advanced age, end-stage renal disease (ESRD), advanced cardiovascular or cerebrovascular disease, or other co-morbidities that may lead to reduced life span.

Achievement of normal or near normal blood glucose levels requires education in self-management techniques including:

- Self blood glucose monitoring
- Recognition, treatment, and prevention of hypoglycemia
- Prevention, early detection, and treatment of chronic complications
- Medical nutrition therapy
- Regular physical activity
- Reinforcement and continuing education

For individuals who have been unable to achieve optimal blood glucose control through dietary changes and regular physical activity, the use of a single antidiabetic oral agent is recommended. Sulfonylureas, metformin, meglitinides, alpha glucosidase inhibitors, and thiazolidinediones are all approved by the U.S. Food and Drug Administration (FDA) for monotherapy. The choice of a particular agent must depend however, on the individual´s characteristics. See the original guideline document for an algorithm to assist in the choice of a pharmaceutical agent.

In case of monotherapy failure, combination therapies may be attempted. If, despite the use of oral agent combination therapy glycemic control is not achieved

or maintained, insulin must be used, either alone or in combination with an indicated oral drug regimen. The total daily insulin doses range from 0.4-1.2 U/kg/day. Please be aware that in insulin resistant patients, doses of > 1.5 U/kg/day may be required.

Choice of specific agents should be based on self-monitoring of blood glucose (SMBG) profiles and physician preference. Remember to evaluate the patient´s cardiac, renal, and hepatic function as appropriate for each oral agent. The choice of an additional agent depends on the patient´s SMBG patterns and clinical scenario. See the original guideline document for an algorithm on combination therapy in type 2 diabetes.

Cardiovascular Risk Reduction Guidelines

Summary of Cholesterol Lowering Therapy

While many organizations (National Cholesterol Education Program [NCEP], American Heart Association [AHA] and others) have developed guidelines for screening and treatment of hypercholesterolemia, controversy exists over specific screening recommendations. There is, however, agreement that reduction of elevated cholesterol levels, along with attention to all modifiable cardiac risk factors, will decrease the incidence of cardiovascular disease. Aggressive treatment of diabetic dyslipidemia will reduce the risk of coronary heart disease (CHD) in patients with diabetes.

Category of Risk Based on Lipoprotein Levels in Adults

Risk	LDL cholesterol	HDL cholesterol	Triglycerides
Very High	≥ 190 mg/dl		≥ 500 mg/dl
High	≥ 130 mg/dl	< 40 mg/dl	≥ 200-499 mg/dl
Borderline	100-129 mg/dl		150-199 mg/dl
Low	< 100 mg/dl	≥ 60 mg/dl	< 150 mg/dl

Abbreviations: LDL, low-density lipoprotein; HDL, high-density lipoprotein

Treatment Decisions Based on LDL Cholesterol Level in Adults with Diabetes

Contributing Risk Factor	Medical Nutrition Therapy (MNT)		Drug Therapy	
	Initiation level	LDL goal	Initiation level	LDL goal
Presence of	≥ 100	< 100 mg/dl	≥ 130	< 100 mg/dl

diabetes	mg/dl		mg/dl	

Abbreviation: LDL, low-density lipoprotein

Note:

1. Medical nutrition therapy (MNT) should be attempted for 3 to 6 months if LDL is close to goal (i.e., 100-130), but pharmacological therapy is indicated upfront if LDL is $\geq$ 130.
2. Since men and women with diabetes are considered to have equal coronary heart disease (CHD) risk, age and sex are not considered risk factors.

ACE Inhibitor Therapy in Diabetes

Evidence suggests that the use of an angiotensin-converting enzyme (ACE) inhibitor in individuals who are at high risk for cardiovascular events may reduce the rates of these events. This includes people with diabetes. Reductions have been seen in myocardial infarction, stroke, coronary revascularization, cardiac arrest, heart failure, and death rates. Evidence also suggests that treatment with an ACE inhibitor slows the progression of microalbuminuria among patients with type 1 diabetes, even if normotensive. Refer also to the Hypertension and Nephropathy sections.

Aspirin Therapy in Diabetes

Both men and women with diabetes have a two- to four-fold increased risk of dying from the complications of cardiovascular disease. Evidence suggests that aspirin therapy should be prescribed as a secondary prevention strategy and, if no contraindications exist, should also be used as a primary prevention strategy in men and women with diabetes. Use of aspirin has not been studied in individuals under the age of 30.

Recommendations*

1. Aspirin therapy is indicated for all persons with diabetes, unless contraindications exist.
2. Use enteric coated aspirin in doses up to 325 mg, once per day.
3. People with aspirin allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal (GI) bleeding, and clinically active hepatic disease are not candidates for aspirin therapy.

*There continues to be controversy in the literature regarding the interaction between aspirin and angiotensin-converting enzyme (ACE) inhibitors.

Hypertension

Introduction

Hypertension contributes to the development and progression of chronic complications of diabetes. The primary goal of therapy for adults should be to

decrease blood pressure to < 130/80. Epidemiological analysis of the United Kingdom Prospective Diabetes Study (UKPDS) showed a continuous relationship between the level of systolic blood pressure and the risk of stroke, diabetes-related deaths, heart failure, microvascular complications, and visual loss.

Lifestyle modifications such as weight loss, exercise, and prudent reduction of salt and alcohol should be a major aspect of treatment of hypertension. Home blood pressure monitors also have a role in helping to manage hypertension aggressively in people with diabetes. Medications should be added to lifestyle changes if those interventions are not successful in controlling hypertension.

The criteria for identification of hypertension in diabetes has been established by the American Diabetes Association (ADA) as a systolic blood pressure (SBP) equal to or greater than 130 mmHg, or a diastolic blood pressure (DBP) equal to or greater than 80 mmHg, or taking antihypertensive medication. The determination of hypertension is based on the average of two or more readings taken at each of two more visits after an initial screening. Isolated systolic hypertension is defined as a systolic blood pressure of 140 mmHg or greater with diastolic blood pressure below 90 mmHg. When systolic and diastolic blood pressures fall into different categories, the higher category should be used to determine the individual's blood pressure status. The American Diabetes Association (ADA) criteria for hypertension differ from the National Heart, Lung and Blood Institute (NHLBI) definition, which states that the presence of diabetes is considered a coronary heart disease (CHD) risk equivalent. The presence of diabetes confers a high risk of new coronary heart disease within ten years.

Benefit of Aggressive Treatment

The results of the United Kingdom Prospective Diabetes Study (UKPDS) blood pressure study indicate that aggressive treatment of even mild-to-moderate hypertension is beneficial. Continued reduction of blood pressure into the normal range resulted in fewer complications. Both systolic and diastolic hypertension markedly accelerate the progression of diabetic nephropathy. Control of hypertension has been demonstrated conclusively to reduce the rate and progression of nephropathy and to reduce the complications of cerebrovascular disease and cardiovascular disease.

Goals of Treatment

In non-pregnant diabetic patients $\geq$ 18 years of age, the primary goal for therapy is to decrease blood pressure to and maintain it at < 130 mmHg systolic and < 80 mmHg diastolic. For patients with isolated systolic hypertension of $\geq$ 180 mmHg, the initial goal is to decrease the systolic blood pressure to < 160 mmHg, and to lower the systolic pressure by 20 mmHg for those with systolic pressures between 160-179 mmHg. If these initial goals are met and well tolerated, further lowering to 140 mmHg may be indicated.

Category	Goal	Initial Therapy
All non-pregnant	< 130/80 mmHg	Lifestyle modifications:

diabetic patients ≥ 18 years of age		weight loss, exercise, reduced salt and alcohol
Isolated SBP 160-179 mmHg	Lower SBP by 20 mmHg, Then < 130/80 mmHg	Lifestyle modifications, see above Antihypertensive medications
Isolated SBP ≥ 180 mmHg	SBP < 160 mmHg, Then < 130/80 mmHg	Lifestyle modifications, see above Antihypertensive medications

Abbreviation: SBP, systolic blood pressure

ACE Inhibitor Use

Evidence suggests that the use of an angiotensin-converting enzyme (ACE) inhibitor in individuals who are at high risk for cardiovascular events may reduce the rates of these events. This includes people with diabetes. Reductions have been seen in myocardial infarction, stroke, coronary revascularization, cardiac arrest, heart failure, and death rates. Evidence also suggests that treatment with an ACE inhibitor slows the progression of microalbuminuria among patients with type 1 diabetes, even if normotensive. Refer also to the Nephropathy section.

Diabetic Nephropathy Guidelines

The earliest clinical evidence of nephropathy is the appearance of low but abnormal levels (30-300 mg/day or 20-200 micrograms/min) of albumin in the urine, referred to as microalbuminuria. Microalbuminuria, a harbinger of renal failure and cardiovascular complications in diabetes, is an albumin concentration in the urine that is greater than normal (but is not detectable with common urine dipstick assays for protein).

Screening for Albuminuria

Routine screening for microalbumin should be performed yearly in adults with type 2 diabetes. If the screening is positive for microalbumin, a quantitative measure is helpful in developing a treatment plan.

After the initial screening and in the absence of previously demonstrated microalbuminuria, a test for the presence of microalbuminuria should be performed annually.

Three methods to screen for microalbuminuria are shown below:

1. Measurement of the albumin to creatinine ratio in a random spot collection
2. 24-hour urine collection with creatinine, allowing the simultaneous measurement of creatinine clearance
3. Timed (4-hour or overnight) urine collection

The first method is often preferred in an office-based setting and generally provides accurate information. There is marked day-to-day variability in albumin excretion, so at least 2 of 3 samples done in a 3- to 6-month period should show elevated levels before designating a patient as having microalbuminuria. If normal, repeat yearly.

Screening for microalbumin with dipsticks or reagent tablets may also be done if assays are not readily available. Reagents and tablets show a 95% sensitivity when performed by trained personnel. All positive tests by reagent strips or tablets should be confirmed using one of the quantitative urine assays listed below.

Category	Spot Collection (micrograms/mg creatinine)	24 Hour Collection (mg/24 hours)	Timed Collection (micrograms/min)
Normal	<30	<30	<20
Microalbuminuria	30-300	30-300	20-200
Clinical Albuminuria	>300	>300	>200

Several factors may influence the albumin excretion rate. Screening should be postponed in the following situations: short term hyperglycemia, exercise, marked hypertension, urinary tract infection, acute febrile illness, or heart failure. Angiotensin-converting enzyme (ACE) inhibitors or nonsteroidal anti-inflammatory drugs (NSAIDs) may also influence results.

Hypertension and Nephropathy

Both systolic and diastolic hypertension markedly accelerate the progression of diabetic nephropathy. Control of hypertension--regardless of agent used--has been demonstrated conclusively to reduce the rate and progression of nephropathy and to reduce the complications of cerebrovascular disease and cardiovascular disease. Refer also to the Cardiovascular and Hypertension sections.

In patients with underlying nephropathy, treatment with ACE inhibitors should also be part of initial therapy. Angiotensin-converting enzyme inhibitors are recommended for all type 1 patients with microalbuminuria, even if normotensive. The use of ACE inhibitors in normotensive type 2 diabetic patients is less well substantiated. For type 2 patients with hypertension or progressive albuminuria, ACE inhibitors are recommended. When ACE inhibitors are contraindicated, other antihypertensive agents should be used. Angiotensin II receptor blockers are being studied in humans with regard to renal protective effects.

Foot Inspection and Monofilament Use Guidelines

- A visual foot examination is recommended at every visit.
- A more in-depth inspection should be performed at least annually to identify high-risk foot conditions.
- An in-depth exam should include an assessment of:
    - Protective sensation
    - Vascular status
    - Skin integrity
    - Foot structure/biomechanics

Risk Identification

Amputation is most commonly the eventual result of previous minor trauma causing foot injury. The two most common causes of minor foot trauma are ill-fitting new shoes and improper cutting of toenails. The risk of ulcers or amputations is increased in people who have had diabetes $\geq$10 years, are male, have poor glucose control, smoke, or have cardiovascular, retinal, or renal complications. Four foot-related conditions are associated with amputation:

1. Peripheral neuropathy
2. Peripheral vascular disease (PVD)
3. History of ulcers or amputation in the other limb
4. Altered biomechanics
    - Evidence of increased pressure (callus, erythema)
    - Limited joint mobility, bony deformity, or nail pathology

Assessing Protective Sensation
(Use either the Semmes-Weinstein monofilament or a tuning fork.)

- Have the patient look away or close his or her eyes.
- Hold the filament perpendicular to the skin.
- Avoiding any ulcers, calluses or sores, touch the monofilament to the skin until it bends. Hold in place for approximately 1.5 seconds, then gently remove it.
- Randomly test the sites shown on the foot diagram provided in the original guideline document.
- Elicit a response from the patient at each site. Lack of sensation at any site may indicate diabetic neuropathy.
- The monofilament may be cleaned with 1:10 sodium hypochlorite solution if contaminated with blood or body fluids.

Risk Category

Low Risk

All of the following:

- Intact protective sensation
- Pedal pulses present
- No severe deformity
- No prior foot ulcer
- No amputation

High Risk

One or more of the following:

- Loss of protective sensation
- Absent pedal pulses
- Severe foot deformity
- History of foot ulcer
- Prior amputation

Management Guidelines

Low Risk

- Visual foot exam every routine diabetes visit
- Annual comprehensive lower extremity sensory exam
- Assess/recommend appropriate footwear
- Provide patient education for preventive self-care

High Risk

- Conduct comprehensive lower extremity exam every 3-6 months
- Demonstrate preventive self-care of the feet
- Refer to specialists and diabetes educator as indicated
- Assess/prescribe appropriate footwear
- Certify Medicare patients for therapeutic shoe benefits
- Note "High Risk Feet" on medical record

See the original guideline document for a list of monofilament resources.

Medical Nutrition Therapy

Purpose

To assist patients in acquiring and maintaining the knowledge, skills, and behaviors to successfully meet the challenges of daily diabetes self-management. Without adequate nutrition advice or an individualized meal plan, patients may have difficulty achieving optimal blood glucose control.

Goals

- Achieve and maintain near normal blood glucose levels by balancing food intake with medication and physical activity
- Achieve optimal serum lipid levels
- Provide adequate calories for attaining and maintaining reasonable weight
- Prevent and treat the acute and long-term complications of diabetes
- Improve overall health through optimum nutrition

Basic Education

For newly diagnosed patients or patients not recently educated about their diabetes. Basic survival skills should include:

- Relationship of food and meals to blood glucose levels, medication, and activity
- Basic food/meal plan guidelines
- Consistent times each day for meals and snacks
- Recognition, prevention, and treatment of hypoglycemia
- Sick day management
- Self-monitoring of blood glucose

Essential Education for Ongoing Nutrition Self-Management

For patients recently diagnosed with diabetes who have been taught basic survival skills or those who have not received current nutrition education. Others who may benefit from nutrition self-management education include patients having difficulties with diabetes management or those experiencing changes in lifestyle, medication, weight, or childbearing status. Follow-up sessions should focus on increasing the patient's knowledge, skills, and flexibility as he or she gains experience living with diabetes.

- Sources of nutrients and their effect on blood glucose and lipid levels
- Label reading and grocery shopping guidelines
- Dining out
- Modifying fat intake
- Use of sugar-containing foods, dietetic foods, and sweeteners
- Alcohol guidelines
- Using blood glucose self-monitoring for glucose pattern control
- Adjusting meal times
- Adjusting food for exercise
- Special occasions, holidays
- Travel, schedule changes
- Vitamin and mineral supplementation

Diabetes Self Management Training

Purpose

To provide patients with the management skills necessary to achieve optimal control of their diabetes. To assist people with diabetes to become effective self-directed decision makers for their own diabetes care, health and well-being. Without comprehension of the relationship between home blood glucose readings, meal planning, and physical activity, patients with diabetes will be hindered in their ability to achieve optimal blood glucose control, and be at higher risk for long term complications.

Goals

- Comprehend the relationship between meals, exercise, medication, and blood glucose monitoring routines

- Correctly identify, treat, and prevent the acute complications of diabetes: hyper- and hypoglycemia
- Prevent or delay the chronic complications of diabetes
- Enhance patient participation in the physician's diabetes treatment plan and improve patient confidence in self-management skills
- Decrease health care costs by reducing the need for expensive hospital stays and the treatment of complications

Basic Education

Overview

- Nature of diabetes in terms of chronicity and metabolism
- Differences between type 1 and type 2 diabetes
- Balance of meals, physical activity and medication, if prescribed

Exercise

- Impact of exercise on blood glucose, lipid levels, hypertension, and body weight

Acute Complications

- Hypoglycemia recognition, causes, treatment, and prevention
- Hyperglycemia recognition, causes, treatment, and prevention

Oral Medication Management

- Action, side effects, timing of dose(s), interactions

Insulin Management

- Action, dosage, onset/peak/duration, pre-loading, mixing, injecting, site selection, storage, syringe disposal
- Use of Glucagon, if appropriate

Self-Monitoring

- Blood glucose meter selection and orientation
- Time(s) to check blood sugar/rationale
- Recording results, reporting to physician
- Disposal of lancets and contaminated materials
- Performance of urinary ketone testing, if appropriate

Continuing Education

Overview

- Benefits of optimal diabetes control and factors that influence it
- Effects of insulin resistance, deficiency, and excess

- Treatment of insulin resistance through weight loss, activity, and medication

Exercise

- Exercise planning appropriate to age, ability, interest, and willingness
- Complication avoidance during exercise

Oral Medication Management

- Action times and maximum dose
- Influences of other medications on blood glucose and possible interactions with oral diabetes medications

Insulin Management

- Methods of storing and adjusting insulin during travel
- Syringe reuse: techniques, benefits, and risks

Self-Monitoring

- Use of self-monitoring of blood glucose to adjust the treatment plan based on approved guidelines
- Establish glycated hemoglobin targets

Complication Prevention and Recognition

- Self foot care, early detection of problems, importance of timely access to care
- Early recognition of eye disease and need for complete eye exam annually
- Impact of lipids, importance of monitoring annually or every two years if values fall within accepted risk levels
- Importance of blood pressure control, need for regular monitoring
- Identification of the symptoms, treatment, and major factors of preventing kidney disease, peripheral vascular disease, cardiovascular disease, periodontal disease, and neuropathy

<u>Smoking Intervention Model</u>

ASK About Smoking at Every Visit
Document in Chart

ADVISE All Smokers to Quit
Advice should be clear, strong, and personalized

ASSIST Smokers in Quitting
Assess motivation to make a quit attempt

Ready to Quit Now

- Identify reasons for wanting to quit

- Develop a quit plan
    - Set quit date within 2 weeks
    - Review previous quit attempts
    - Identify smoking triggers and challenges
    - Brainstorm strategies
    - Inform family, friends, and co-workers
- Provide self-help materials and referrals
- Encourage nicotine replacement therapy (NRT): patch, gum, nasal spray, inhaler or non-nicotine replacement therapy (bupropion-SR), unless contraindicated
- Give advice on successful quitting
    - Total abstinence
    - Avoid alcohol
    - Plan for dealing with smokers in the house

Not Ready to Quit Now

- Use the 4Rs to enhance motivation
    - Relevance: Provide patient-specific information
    - Risks: Ask patient to identify negative consequences
    - Rewards: Ask patient to identify benefits
    - Repetition: Repeat every visit

ARRANGE Follow-up

If Quit (Relapse Prevention)

- Congratulate, encourage maintenance
- Review benefits from cessation
- Review successes during quit period
- Review problems encountered, offer possible solutions
- Anticipate problems or threats to maintenance, such as weight gain, depression, or prolonged withdrawal

Timing

Contact soon after the quit date, preferably within the first week; further follow-up as needed.

If Quit Attempt Unsuccessful

- Ask for recommitment to total abstinence
- Remind patient to use lapse as a learning experience
- Review circumstance that caused lapse
- Develop new plan with patient

Timing

Contact soon after new quit date, preferably during the first week; further contacts as needed based on new quit plan.

For information on smoking cessation programs, or to obtain a copy of a wallet card containing this information, call The Center for Tobacco Prevention and Control at (508) 856-4099.

Massachusetts Guidelines for Adult Diabetes Care

History and Physical		
	Frequency	Description
Blood Pressure, Height and Weight	Every 3-6 months	If BP >130/80 initiate measures to lower
Dilated Eye Exam	Annual[1]	Refer to ophthalmologist or optometrist
Foot Exam	Every 3-6 months	Visual exam without shoes and socks every routine diabetes visit
Comprehensive Lower Extremity Sensory Exam	Initial/Annual[2]	Teach protective foot behavior if sensation diminished. Refer to podiatrist if indicated. See Foot Inspection and Monofilament Use Guide
Dental Exam	Every 6 months	Refer to dentist
Smoking Status	Ongoing	Check every visit/Encourage smoking cessation. See Smoking Intervention Model

Labs		
	Frequency	Description
HbA1c	Every 3-6 months[3]	Ideal goal <7.0% or <1% above lab norm. Action required at >8.0%, make changes in regimen
Fasting/Random Blood Glucose	As indicated	Compare lab results with glucose self-monitoring
Fasting Lipid Profile	Annual[4]	See Cardiovascular Risk Reduction Guidelines
Urine Microalbumin/Creatinine	Initial/Annual[5, 6]	If abnormal, recheck x2 in a 3-month period then treat if 2 out of 3 collections show elevated levels

Serum Creatinine	Initial/As Indicated	
EKG	Initial	If patient is >40 years old or DM ≥10 years
Thyroid Assessment	Initial/As Indicated	Thyroid palpation, thyroid function test(s) if indicated

Recommended Immunizations		
	Frequency	Description
Flu Vaccine	Every fall	
Pneumovax	Recommended once	Also revaccination x1 if ≥65 and first vaccine >5 years ago and patient age <65 at time of 1st vaccine

Self-Management		
	Frequency	Description
Review Self-Management Skills	Initial/Ongoing	
Review Treatment Plan	Initial/Ongoing	Check self-monitoring log book, diet, exercise, and meds
Review Education Plan	Initial/Ongoing	Refer for Diabetes Self-Management Training if indicated

Counseling		
	Frequency	Description
Review Nutrition Plan	Initial/Ongoing	Refer for medical nutrition therapy if indicated
Review Physical Activity Plan	Initial/Ongoing	Assess/Prescribe based on patient's health status
Tobacco Use	Annual/Ongoing	Assess readiness/Counsel cessation/Refer
Psychosocial Adjustment	Annual/Ongoing	Suggest diabetes support group/Counsel/Refer
Sexuality/Impotence/Erectile	Annual/Ongoing	Discuss diagnostic evaluation

Dysfunction		and therapeutic options
Preconception/Pregnancy	Initial/Ongoing	Need for tight glucose control 3-6 months preconception. Consider early referral to OB/GYN

Abbreviations: BP, blood pressure; HbA1c, glycated hemoglobin; EKG, electrocardiogram; DM, diabetes mellitus; OB/GYN, obstetrician/gynecologist

[1]Type 1: Initial exam after 5 years disease duration.
[2]Every 3-6 months if patient has high-risk foot conditions.
[3]Two times per year for stable glycemic control. Four times per year if change in therapy or if not meeting glycemic goals.
[4]If values fall in lower risk levels, assessment may be repeated every 2 years.
[5]Initial urinalysis at diagnosis of diabetes, annual microalbumin thereafter in absence of microalbuminuria.
[6]Type 1: Initial exam to begin with puberty and after 5 years disease duration.

Note: A flow sheet for diabetes care is included in the original guideline document.

CLINICAL ALGORITHM(S)

Algorithms are provided for:

- New Mild-Moderate Type 2 Diabetes First Line Therapy
- Combination Therapy in Type 2 Diabetes

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations were based on a comprehensive review of published reports, in particular the American Diabetes Assocation 2001 Clinical Practice Recommendations. Other sources of evidence are identified throughout the guideline document. In cases where the data did not appear conclusive, recommendations were based on the consensus opinion of the group.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefits

Appropriate identification and management of adults who have diabetes mellitus.

Cardiovascular Risk Reduction

The following can decrease the incidence of cardiovascular disease in patients with diabetes mellitus:

- Reduction of elevated cholesterol levels, along with attention to all modifiable cardiac risk factors (including the reduction of blood pressure)
- Aggressive treatment of diabetic dyslipidemia
- Use of an angiotensin-converting enzyme (ACE) inhibitor
- Aspirin therapy*

*There continues to be controversy in the literature regarding the interaction between aspirin therapy and ACE inhibitors.

Diabetic Nephropathy

- Annual screening for microalbuminuria will allow early identification of patients with nephropathy.
- Improving glycemic control, aggressive antihypertensive treatment, and the use of ACE inhibitors will slow the progression of nephropathy.
- Both systolic and diastolic hypertension markedly accelerate the progression of diabetic nephropathy. Control of hypertension has been demonstrated conclusively to reduce the rate and progression of nephropathy and to reduce the complications of cerebrovascular disease and cardiovascular disease.

Foot Inspection and Monofilament Use

Early recognition and management of risk factors for ulcers and amputations can delay the onset of adverse outcomes.

Medical Nutrition Therapy and Diabetes Self-Management Training

Medical nutrition therapy and diabetes self-management training provide a patient with diabetes the knowledge and skills to perform self-care on a day-to-day basis to achieve and maintain optimal glucose control.

Determining Body Mass Index (BMI)

Obesity substantially raises the risk of morbidity from type 2 diabetes and other diseases. The BMI describes relative weight for height and is significantly correlated with total body fat content. The BMI may be used to assess overweight and obesity and to monitor changes in body weight. See the table titled: Determining Body Mass Index from Height and Weight and Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risk in the original guideline document.

POTENTIAL HARMS

First Generation Sulfonylureas

- All sulfonylureas may cause hypoglycemia.
- Chlorpropamide (Diabenese): Use caution in elders with renal disease. Can cause hyponatremia; alcohol may cause antabuse-like reaction.

Second Generation Sulfonylureas

Glyburide/metformin (Glucovance): May cause hypoglycemia. Major side effects are gastrointestinal (GI) symptoms. Lactic acidosis may occur, therefore it is contraindicated in patients with renal insufficiency, chronic metabolic acidosis, or congestive heart failure (CHF). Temporarily discontinue for surgery or for radiology procedures involving contrast media.

Meglitinides

- Repaglinide (Prandin): Patients who skip or add a meal should be instructed to skip or add a dose for that meal. May cause hypoglycemia.
- Nateglinide (Starlix): Use with caution in chronic liver disease. May cause hypoglycemia. Patients who skip a meal should also skip that dose of nateglinide to reduce the risk of hypoglycemia. Should not be added to regimens of patients who have not been adequately controlled by glyburide or other insulin secretagogues, nor should these patients be switched to nateglinide.

Alpha Glucosidase Inhibitors

Acarbose (Precose), miglitol (Glyset): Delays absorption of starch after a meal. Most common side effect is excessive flatulence, diarrhea and abdominal pain. Contraindicated in diabetic ketoacidosis (DKA), inflammatory bowel disease, colonic ulceration or partial intestinal obstruction.
If hypoglycemia occurs in patients who are being treated with either Precose or Glyset as well as either insulin or sulfonylureas, it MUST be treated with glucose, not sucrose or complex carbohydrates.

Biguanides

Metformin (Glucophage), metfomin extended release (Glucophage XR), glyburide/metformin (Glucovance): Take with food to lessen gastrointestinal side effects. Do not use with impaired renal or hepatic function. Discontinue for surgical and intravenous (IV) contrast dye procedures.

Thiazolidinediones*

Rosiglitazone (Avandia), pioglitazone (Actos): Use with caution in the presence of hepatic disease. Do not use with patients who have discontinued troglitazone (Rezulin)* therapy due to jaundice or hepatic disease. Monitor baseline liver function when initiating therapy, then test every 2 months for one year, then periodically as clinically indicated. May cause anovulatory premenopausal women to resume ovulation. In-vitro studies do not suggest any clinically relevant effect on the metabolism of oral contraceptives (OC). However, because of past experience with another thiazolidinedione*, caution should be exercised with patients receiving Actos or Avandia and an oral contraceptive. Thiazolidenediones may increase high-density lipoprotein (HDL) and low-density lipoprotein (LDL) levels. The long-term effects are not known.

*Troglitazone (Rezulin) was removed from the market in March 2000 by the U.S. Food and Drug Administration (FDA) after being linked to liver failure, liver transplants, and deaths.

CONTRAINDICATIONS

CONTRAINDICATIONS

Second Generation Sulfonylureas

Glyburide/metformin (Glucovance): Contraindicated in patients with renal insufficiency, chronic metabolic acidosis, or congestive heart failure (CHF).

Alpha Glucosidase Inhibitors

Acarbose (Precose), miglitol (Glyset): Contraindicated in patients with diabetic ketoacidosis (DKA), inflammatory bowel disease, colonic ulceration or partial intestinal obstruction.

Biguanides

Metformin (Glucophage), metfomin extended release (Glucophage XR), glyburide/metformin (Glucovance): Do not use in patients with impaired renal or hepatic function.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines are not intended to replace the clinical judgment of primary care providers, nor are they intended to preclude more extensive evaluation and management of the patient by other specialists as needed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Massachusetts Department of Public Health mailed the guidelines to all primary care physicians, endocrinologists, and certified diabetes educators in the state. Nurse practitioners and physician assistants also received information on the guidelines' availability.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Massachusetts Department of Public Health: Diabetes Control Program, Diabetes Guidelines Work Group. Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health; 2001 Jun. Various p.

ADAPTATION

These guidelines are based on the American Diabetes Association 2001 Clinical Practice Recommendations.

DATE RELEASED

1999 Jun (revised 2001 Jun)

GUIDELINE DEVELOPER(S)

Massachusetts Department of Public Health, Bureau of Family and Community Health, Diabetes Control Program - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

Massachusetts Department of Public Health, and the managed care organizations that endorsed the guidelines.

GUIDELINE COMMITTEE

Diabetes Guidelines Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Kate Alich, MS, RD; Lloyd Axelrod, MD; Darcy Bacall, RN, CDE, BSN; Evan Benjamin, MD; Kathleen Bennett, MD; Ralph Blair, MD; Melanie Brunt, MD; Stuart Chipkin, MD; Alan Drabkin, MD; Laurie Gyscek, RN, BSN; Beverly Holt-Halford, RD, MPH; Marlene Kane, RN, BSN, CPHQ; Frances Hesse Larkin, RN, MS, CDE; Chih Wei Lee, MPH; Ann Lovett, RN, MA; B. Dale Magee, MD; Roseanna H. Means, MD, MSc; Paul Mendis, MD; Ann Naughton, RPh, MBA; Randy Peto, MD, MPH; Gary I. Portnay, MD; Carla Rosenkrans, RN, MPH; Ann Marie Sciammacco, RN, MSN; Jo Seibel, MD; Debra Sylvester; Gisele Thornhill, MD, MPH; Theresa Trainor, LPN, BS; Barry Zallen, MD, FAAP

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

Baystate Health System - Hospital/Medical Center
Blue Cross Blue Shield of Massachusetts - Managed Care Organization
Boston Medical Center HealthNet Plan - Managed Care Organization
Division of Medical Assistance, Primary Care Clinician (PCC) Plan - State/Local Government Agency [U.S.]
Fallon Health Care System - Managed Care Organization
Harvard Pilgrim Health Care, Inc. - Managed Care Organization
Massachusetts Department of Public Health - State/Local Government Agency [U.S.]
Massachusetts League of Community Health Centers - Hospital/Medical Center
Massachusetts Medical Society - Professional Association
MassPRO - Private Nonprofit Organization
Neighborhood Health Plan - Managed Care Organization
Network Health - Managed Care Organization
Partners/MGH - Managed Care Organization
Tufts Health Plan - Managed Care Organization

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously released version: Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health--Diabetes Control Program; 1999 Jun. Various p.

The guidelines are reviewed and revised on a regular basis.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Massachusetts Department of Public Health Web site.

Print copies: Available from the Massachusetts Health Promotion Clearinghouse, The Medical Foundation, 95 Berkeley Street, Boston MA 02116; Fax: (617) 536-8012; Web site: www.maclearinghouse.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Massachusetts guidelines for adult diabetes care (laminated card). Boston (MA): Massachusetts Department of Public Health--Diabetes Control Program, 2001. Electronic copies available in Portable Document Format (PDF) from the Massachusetts Department of Public Health Web site.

Print copies: Available from the Massachusetts Health Promotion Clearinghouse, The Medical Foundation, 95 Berkeley Street, Boston MA 02116; Fax: (617) 536-8012; Web site: www.maclearinghouse.com.

PATIENT RESOURCES

The following is available:

- Diabetes care card (patient wallet card). Boston (MA): Massachusetts Department of Public Health--Diabetes Control Program, 2001. Electronic copies available in Portable Document Format (PDF) from the Massachusetts Department of Public Health Web site.
- Additional diabetes brochures are available in PDF format from the Massachusetts Department of Public Health Web site.

Print copies: Available from the Massachusetts Health Promotion Clearinghouse, The Medical Foundation, 95 Berkeley Street, Boston MA 02116; Fax: (617) 536-8012; Web site: www.maclearinghouse.com.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on April 28, 2001. It was verified by the guideline developer as of May 23, 2001. This summary was updated by ECRI on November 12, 2002.

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Date Modified: 11/1/2004